

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION
THIS DOCUMENT RELATES TO: ALL ACTIONS

Master Civil No. 01-cv-12257

MDL No. 1456

Judge Patti B. Saris

**PLAINTIFFS' COMBINED OPPOSITION TO THE J&J DEFENDANTS'
POST-REMAND MOTIONS FOR SUMMARY JUDGMENT**

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James Shepley, on behalf of the estate of Therese Shepley, and Larry Young, on behalf of the Estate of Patricia Young, by their undersigned counsel, respectfully submit this Combined Opposition to the J&J Defendants' Post-Remand Motion for Summary Judgment Against Class 1 Residents of the Commonwealth of Massachusetts (Dkt. No. 6668) ("J&J Mass. MSJ") and the J&J Defendants' Post-Remand Motion for Summary Judgment Against Class 1 Residents of the District of Columbia and States Other Than the Commonwealth of Massachusetts (Dkt. No. 6672) ("J&J Nationwide MSJ"). For the reasons set forth below, J&J's post-remand summary judgment motions should be denied.

I. INTRODUCTION

Throughout this litigation, the Court has observed that "Class 1 is different." *See, e.g.*, Ex. 16 (Hearing Tr. (5/23/06) at 64:21-25).¹ Although the Class 1 members were required by law to make co-payments based on AWP, these sick and elderly consumers did not know what AWP meant, let alone that J&J was inflating the AWP. Nor did the Class 1 members know that, due to J&J's conduct, physicians charged with making decisions that might save their lives were profiting from the drugs they prescribed. Despite these distinguishing facts, and despite the fact that no Medicare beneficiary appeared at the Class 2/Class 3 bench trial to testify on behalf of Class 1, J&J urges this Court to dispatch with Class 1's claims and to enter summary judgment against the Class and in favor of the J&J Defendants (sometimes hereafter "J&J"). J&J's motions should be denied.

J&J asks the Court to revisit its prior rulings on government knowledge by imputing the Government's purported "knowledge" to Class 1. But we have been down this road before. Prior to trial, J&J moved for summary judgment as to Class 1. *See* Dkt. No. 2274. J&J assumed

¹ All exhibits to this brief are attached to the Declaration of Steve W. Berman submitted herewith.

for the purpose of that motion that “plaintiffs will abandon the theory that AWP equals ASP for Classes 1 and 2” on the basis that Defendants “demolished” the argument that the federal Government intended the “speed limit” to be zero. Dkt. No. 2670, at 2. In other words, J&J previously sought summary judgment on the basis of the Government’s alleged knowledge of the conduct challenged in this litigation. In response, Plaintiffs argued, among other things, that there were disputed issues of fact “regarding whether the government knew the degree by which AWPs exceeded acquisition cost.” Plaintiffs’ Opp. to the J&J Defs’ Mot. for Summ. J. (Apr. 7, 2006) at 3. The Court denied J&J’s motion and, after trial, found that, regardless of the Government’s knowledge, that knowledge did not “exonerate defendants.” *In re Pharm. Indus. Average Wholesale Price Litig.* (“*In re AWP*”), 491 F. Supp. 2d 20, 94 (D. Mass. 2007); *see also id.* at 95 (“neither the TPPs nor the government could move quickly or effectively to fix the problem”). J&J has provided no basis for this Court to reverse its finding that any purported government knowledge absolves J&J.

The Court has likewise already rejected J&J’s argument that the Government’s knowledge be “imputed” to other Classes, holding: “Defendants make a strained argument that Medicare’s knowledge of mega-spreads should be imputed to the TPPs in the MediGap Class. However, Medicare was not the agent of the TPPs that had contracts to reimburse beneficiaries, and Medicare did not set or approve drug prices.” *In re AWP*, 252 F.R.D. 83, 97 n.32 (D. Mass. 2008).

A similar result obtains here. There is no basis to impute the “knowledge” of the Government to Class 1, because there is no agency relationship between Class 1 and the Government and J&J’s attempt to expand the “learned intermediary” doctrine to apply in this context is inappropriate where the Government *could not have acted* even if it had the

knowledge J&J claims. Further, even if the Court holds as a matter of law that the knowledge of the Government may be imputed to Class 1, it should not do so here because, at a minimum, there are genuine issues of material fact regarding J&J's efforts to *conceal* its conduct from the Medicare program.

There are other reasons why J&J's motions should be denied. J&J's motions fail because they ignore the fact that the vast majority of Class 1's claims (all except California, Illinois, Massachusetts, New Hampshire and Nebraska) mandate that Plaintiffs' claims be tried to a jury. The right to a jury trial is protected by the Seventh Amendment. Importantly, it is the jury's role to decide disputed issues of fact and to determine damages. For example, while the Court determined what was "unfair" based upon a three-part test, a jury could, once properly instructed on the law, decide to use different factors or to weight those factors differently. In addition, at the Class 2/Class 3 trial, Plaintiffs suggested that the Court could apply a benchmark different than the 30% benchmark used by Dr. Hartman for Class 2 and Class 3. While the Court rejected those positions, a jury could decide otherwise – or decide to adopt another damages methodology altogether. The Court cannot enter judgment against Class 1 without giving the jury that opportunity.

Finally, J&J seeks to dismiss all of Class 1's non-Massachusetts state-law claims on various grounds. Most importantly, J&J's arguments ignore the rights in most states to a jury trial and ignore that any knowledge of the Government cannot be imputed to Class 1. The Court cannot simply apply its Class 2/Class 3 findings to the consumers in other states as J&J suggests. Rather, on summary judgment, it must, making all inferences in favor of Plaintiffs, allow Class 1's claims to proceed to trial.

II. BACKGROUND

A. Procedural History

Plaintiffs brought this action in 2001 alleging that the pharmaceutical company defendants had unlawfully and fraudulently inflated the AWP's for their drugs. On January 30, 2006, the Court certified three classes against the Track 1 Defendants (including J&J), one of which, Class 1, was certified as a nationwide Class because the Court held there would be no individual issues of causation and reliance. *In re AWP*, 232 F.R.D. 229-31 (D. Mass. 2006). Class members in nine states (Alabama, Alaska, Georgia, Iowa, Kentucky, Louisiana, Mississippi, Montana and Virginia) were excluded from Class 1 on the grounds that the laws of those states did not permit class actions.

Beginning November 6, 2006, the Court held a 9-week bench trial for claims brought by Class 2 and Class 3 under Mass. Gen. Laws ch. 93A against AstraZeneca, BMS, J&J and Schering-Plough/Warrick. On June 21, 2007, the Court issued its findings of fact and conclusions of law resulting from the bench trial. Although it found J&J's conduct "troubling" *In re AWP*, 491 F. Supp. 2d at 31, 104, the Court held that J&J's conduct had not damaged the Class. Thereafter, during a pretrial conference regarding Plaintiffs' Class 1 claims against BMS (claims that were ultimately settled), the Court stated that it had, in fact, intended to enter judgment in favor of J&J and against Class 1. *See* Ex. 17 (Hearing Tr. (7/3/07) at 8:3-5 and 8:19-11:3).

Based partially on the comments the Court made during the BMS status conference, the Track 1 Defendants moved the Court to enter final judgment under Fed. R. Civ. P. 54(b). *See* Dkt. Nos. 4616 and 4617. That motion asked the Court, among other things, to enter final judgment in favor of J&J and against Class 1 (in addition to Classes 2 and 3). Likewise, the

Track 1 Defendants submitted a proposed order for the Court to sign in connection with entering final judgment. *See* Dkt. No. 4714. Paragraph 13 of that proposed order provided:

As to the claims of Class 1, Plaintiffs had advocated a ‘zero tolerance’ approach to liability and damages (as they had for Class 2). I rejected this approach. Again, because it was undisputed that the Procrit and Remicade spreads never substantially exceeded the range of spreads Plaintiffs themselves contend were generally expected by industry and government, no reasonable jury could find that the J&J Defendants’ conduct violated the consumer protection laws applied to the Class 1 claims. Accordingly, on July 3, 2007, I noted on the record that the June 21, 2007 order dismissing the J&J Defendants applied to the claims by members of Class 1. (7/30/07 Tr. at 9-10).

Similarly, on November 8, 2007, the Track 1 Defendants moved the Court to “implement” its November 1, 2007 memorandum and order regarding damages. In support of this motion, the Track 1 Defendants noted that the Court’s November 1 order was not complete because it did not “reflect the Court’s stated intention to enter judgment in favor of the J&J Defendants with regard to Class 1.” Dkt. No. 4880, at 2. The proposed order (Exhibit A to their motion) contained language identical to the language set forth above contained in Defendants’ proposed order dated September 14, 2007.

Plaintiffs objected to J&J’s proposed language, noting that:

In addition, part of the proposed finding in paragraph 14 pertaining to Class 1 should be stricken, to wit, the passage stating that “no reasonable jury could find that the J&J Defendants’ conduct violated the consumer protection laws applicable to the Class 1 claims.” Although the Court did indicate during the July 3, 2007 hearing that it would apply the 30% “speed bump” to the Class 1 claims against J&J, it never made a finding that “no reasonable jury could find that the J&J Defendants’ conduct violated the consumer protection laws applicable to the Class 1 claims.” Accordingly, that reference should be deleted as shown in Plaintiffs’ revised proposed order.

Dkt. No. 4881, ¶ 3. The Class 1 representatives also objected to the Track 1 Defendants’ proposed order on the grounds that the claims of the Class 1 plaintiffs had never actually been

adjudicated. *See* Dkt. No. 4643, at 2-3. In a subsequently-submitted Reply Brief on the issue, J&J claimed:

[P]laintiffs object to the passage stating that “no reasonable jury could find that the J&J Defendants’ conduct violated the consumer protection laws applicable to the Class 1 claims.” It is important to retain this passage in the Findings in order to explain to the First Circuit why the Court is entering judgment in favor of the J&J Defendants as to Class 1. In light of plaintiffs’ concession that the J&J Defendants’ subject drugs (Procrit® and Remicade®) never substantially exceeded the range of spreads plaintiffs themselves contend was generally expected by the industry and government, there remains no triable issue of fact as to Procrit® and Remicade® in connection with Class 1. The passage the J&J Defendants propose simply explains why a Class 1 jury trial against the J&J Defendants is not warranted.

Dkt. No. 4882.

The Court subsequently entered final judgment pursuant to Fed. R. Civ. P. 54(b). Dkt. No. 4896. In that order, the Court held:

As to the J&J Defendants, the Court ruled, among other things, that although J&J’s conduct was troubling, it did not violate Mass. Gen. Laws ch. 93A, in part because the spreads on the J&J Defendants’ subject drugs (Procrit® and Remicade®) never substantially exceeded the range of spreads generally expected by the industry and government. 491 F. Supp. 2d at 104. As a result, the Court ruled that the claims of Class 2 and Class 3 should be dismissed. *Id.* at 109. The claims by members of Class 1 are dismissed for the same reason.

Id. at ¶ 13.

On December 19, 2007, the Class 1 representatives filed a Notice of Appeal. Dkt. No. 4954. Because Don Haviland was disqualified as Class Counsel, the First Circuit permitted Class Counsel to substitute themselves as counsel of record on that appeal. Ex. 18 (Feb. 15, 2008 Order). On September 29, 2009, the First Circuit entered an order remanding the Class 1 claims against J&J to this Court. *In re AWP*, 582 F.3d 231 (1st Cir. 2009). In that decision, the First Circuit found that:

It is undisputed that the bench trial adjudicated only claims of Classes 2 and 3, not Class 1. Consequently, it is also undisputed that the Class 1 representatives did not participate in the trial. Finally, it is clear from the record that the imposition of that trigger was based on the district court's fact findings as to how large a spread the Class 2 and Class 3 plaintiffs expected. *See generally In re Pharm.*, 491 F. Supp. 2d 20.

Id. at 236. Against this backdrop, the First Circuit found that this Court's entry of judgment against Class 1 and in favor of J&J was problematic. *Id.* Specifically, the First Circuit found that it had an inadequate basis to determine the procedural posture for the judgment entered against Class 1. The Court noted that the judgment could not have been entered based on this Court's findings at trial because "the Class 1 plaintiffs were not represented before the court in the previous trial," *id.* at 236, and because some of the states in which Class 1 members resided contained jury trial rights. *Id.* It likewise did not believe the judgment could have been entered pursuant to Rule 56 because the Court had not made its findings "with any deference to the Class 1 plaintiffs' potential evidence." *Id.* Therefore, the First Circuit vacated the judgment entered against Class 1 and remanded the matter to this Court to proceed in accordance with its opinion.

At an October 8, 2009 status conference, this Court asked J&J to move for summary judgment, but indicated that it would evaluate such a motion with an eye towards the First Circuit's reminder that many of the state statutes under which this Court has certified claims require jury trials. *See* Ex. 19 (Hearing Tr. (10/8/09) at 10:2-15). On November 23, 2009, J&J filed two post-remand motions for summary judgment, one against the Massachusetts class and the other against the remainder of Class 1.

B. Summary of Facts

At trial, Plaintiffs introduced evidence that (1) J&J knew that AWP was the reimbursement benchmark used by Medicare Part B and most private payors; (2) J&J caused AWPs to be published for its Subject Drugs (Procrit® and Remicade®); (3) J&J's AWPs for its

Subject Drugs were false; and (4) for both Procrit and Remicade, J&J actively marketed the spread. *See* Additional Statements of Disputed Material Fact Regarding J&J's Spread Marketing, Local Rule 56.1 Counter-Statement. After trial, Plaintiffs introduced a Complaint brought by a former Centocor employee where she alleged that she was involved in marketing Remicade by referring to the money that could be made by prescribing the drug. This employee, and others, had used a PowerPoint presentation containing an audible "Ka-Ching!" sound while a slide detailed the profit potential of Remicade. *See* Local Rule 56.1 Counter-Statement ¶ 19. This and other unethical deeds led the Court to conclude that J&J's conduct was "troubling." *In re AWP*, 491 F. Supp. 2d at 31, 104.²

In addition to those findings, the Court found that J&J had actively concealed its conduct from the Government. For example, while Catherine Dooley testified that she had conversations with officials from CMS about the true prices for Procrit, and despite the fact she regularly wrote to her superiors, Ms. Dooley has no notes or memo regarding her meetings. *See* Local Rule 56.1 Counter-Statement No. 4. Nor do any of the millions of documents produced by CMS reflect such conversations. *Id.*

However, Ms. Dooley *did* author several memoranda expressing concerns about the Government learning of Procrit's true price. *Id.* On August 6, 1996, Ms. Dooley warned that if the Government conducted a survey and, in fact, learned of the "significant" discrepancy between AWP and actual acquisition cost for non-End Stage Renal Disease treatment, the likely consequence would be that the Government would take action to lower the reimbursement rate for Procrit providers in non-dialysis. *Id.* When OBI considered taking a price change, it was

² J&J states that it wishes to preserve the right to appeal these findings. J&J Mass. MSJ at 14 n.6. But J&J has waived the right to do so because it did not appeal those findings within 30 days of the entry of final judgment. Indeed, though J&J cross-appealed this Court's entry of judgment, it subsequently voluntarily dismissed that cross-appeal. *See* Ex. 20 (Judgment (1st Cir. June 19, 2008) (granting J&J's unopposed motion to voluntarily dismiss appeal pursuant to Fed. R. App. P. 42(b))).

careful not to raise its list price above that of Epogen because OBI did not want to raise the undue attention of HCFA, which could trigger a pricing survey or investigation by the Government. *Id.* For example, in a memorandum dated December 2, 1997, Ms. Dooley highlighted several key “Implications for Increase over Parity” including: (1) “Change in list price could trigger a drug pricing survey by HCFA,” (2) “You may have a pricing survey anyway, but raising red flags could trigger it earlier,” and (3) “Consequence of pricing survey could be acquisition, FSS or ESRD reimbursement rate in non-dialysis.” *Id.* A day later, Gary Reedy sent a memorandum recommending against OBI taking a price increase above parity for similar reasons: “We feel creating a higher list price could raise undue attention and possibly trigger a drug survey by HCFA because of the difference in list price for the two identical drugs, Procrit and Epogen.” *Id.* Ms. Webb agreed that the risk of triggering a government price survey was a sound basis for advising against OBI taking a greater price increase at that time. *Id.*

J&J’s actions were particularly egregious because J&J also sought to hide from Medicare beneficiaries and other members of the public that it marketed Procrit and Remicade based on the spread and that its AWP’s for those drugs were not real numbers. *See* Local Rule 56.1 Counter-Statement No. 1. OBI knew that consumers were unaware of the discrepancy between AWP and average acquisition cost, and indeed would have been unhappy to learn of it. *Id.* In an e-mail from Cathleen Dooley to Richard Moran dated January 6, 1998, Ms. Dooley highlighted that patients would be surprised to learn that physicians bill patients 20% off AWP, rather than off the lower acquisition cost: “*This will be a sensitive issue because the physician is able to bill Medicare and the patient off of AWP; the patient’s 20% co-pay is higher than it would be if it was billed off of acquisition cost (public relations’ issue).*” *Id.* (emphasis added).

Consequently, Medicare beneficiaries did not know that AWP was unlawfully inflated and thought it was a fair price. Anna Choice testified that “whatever system is used as a basis for calculating my co-payment should be fair and accurate and not subject to manipulation.” Local Rule 56.1 Counter-Statement No. 1. “I feel it is unfair for drug companies to publish prices that have no real meaning, the effect of which is to cause me and others like me to pay more for those drugs.” *Id.*

I understand that defendants say that their published prices are like a sticker price on a car. However, to me a drug company that creates a false price knowing that my life depends on the drugs and that I must pay for them stands in different shoes than a car manufacturer. In addition, I am not aware of any situation where a car manufacturer offers discounts of 30%, 60% or even over 300% off sticker price.

Id. Similarly, Rebecca Anne Hopkins testified that “I do not know why BMS or other manufacturers would try to impose higher costs on me, but I think it is very unfair. Average folks like me have to rely on the honesty of those setting prices.” *Id.*

Larry Young likewise testified that:

My wife and I relied on the advice of my wife’s doctors and their facilities to be fair in their pricing of prescription medications and to comport with all ethical, moral, medical, regulatory and legal standards with respect to their medical care and treatment and their bills.

My wife and I did not know if (or to what extent) her doctors or their facilities profited from the sale of prescription medications, as we were never told.

Id. James E. Shepley further testified that “I relied on the advice of my doctors and their facilities to be fair in their pricing of prescription medications and to comport with all ethical, moral, medical, regulatory and legal standards with respect to their medical care and treatment and their bills.” *Id.*

C. Summary of Damages to Class 1

During the Class 2/Class 3 bench trial, Plaintiffs took two different positions on how damages should be calculated: one position for Class 2 and one position for Class 3.

On November 2, 2006, prior to the beginning of trial, the Court entered its order construing AWP as set forth in the Medicare statute, 42 U.S.C. § 1395u(o) (1998), pursuant to its plain meaning to be “the average price at which wholesalers sell drugs to their customers, including physicians and pharmacies.” *See In re AWP*, 460 F. Supp. 2d 277, 278 (D. Mass. 2006). Based on this ruling, Plaintiffs argued that, for Class 2, the Court should impose “*per se*” liability, meaning that it should impose damages whenever a given defendant’s AWP was above its Actual Selling Price (“ASP”). *See, e.g.*, Plaintiffs’ Post-Trial Findings of Fact (“PFOF”), ¶ 255 (Dkt. No. 3553). Therefore, Dr. Hartman calculated Class 2 spreads based on this theory. In contrast, for Class 3, Plaintiffs argued that Defendants should be liable for damages whenever the spreads between the AWP and ASP on their drugs exceeded thirty percent (30%). Dr. Hartman calculated damages for Class 3 using that yardstick. *Id.*

The majority of the spreads for J&J’s two drugs (Procrit® and Remicade®) were below Dr. Hartman’s 30% “speed limit.” Therefore, based on evidence that developed during trial, Plaintiffs argued during closing arguments this Court should not apply the 30% benchmark to J&J’s drug Remicade® for Class 3. Plaintiffs argued that the Court should instead apply a 25% benchmark, because, unlike substantially all other physician-administered drugs (not just the drugs at issue at trial), J&J set its AWP for Remicade® at 30% above the WAC. *See* Ex. 21 (Trial Tr. Day 21 (1/26/07) at 151:16-152:1 and 156:6-20). Plaintiffs’ proposed Post-Trial Proposed Findings of Fact likewise reflected this position and cited to testimony from a Centocor Vice President that Remicade’s AWP spread had been set at 30% because the company thought

that spread would allow doctors to make a profit and because the company thought insurers would pay that high for Remicade. PFOF, ¶ 183.

Plaintiffs therefore argued that there were some “unique features” of Remicade® that justified applying a benchmark different than the one advocated by Dr. Hartman for the remaining three defendants. PFOF, ¶ 259. Plaintiffs argued that:

First, unlike every other drug discussed in the litigation (and apparently unlike virtually all other drugs) Johnson & Johnson caused the AWP-to-WAC ratio for Remicade to depart starkly from the usual and expected 1.20 or 1.25 multipliers. As to Remicade, Johnson & Johnson caused the AWP-to-WAC markup to be 1.30, *i.e.*, 5 percentage points higher than what is normally expected in the market place for single source, branded products.

Second, it appears that significant difficulties were encountered by Plaintiffs in the acquisition and interpretation of ASP data from Johnson & Johnson. Even Johnson & Johnson’s own expert, Mr. Dukes, testified that his many adjustment to ASP were simply based upon representations that were given to him by counsel for Johnson & Johnson or employees at Johnson & Johnson – representations that he, himself, did not test for accuracy.

Third, while at trial the ‘spread’ between AWP and ASP was typically discussed in terms of percentages, it was also recognized that the ‘spread’ might be measured *n [sic]* by the total dollars involved. After all, large percentages can sometimes mean small dollars, and small percentages can sometimes mean large dollars: Since providers may be motivated by the dollars that he/she might receive by prescribing one drug rather than another, at times the percentages is less relevant than the actual dollars involved. As with Remicade, the dollars are large although the spreads may ‘only’ be close to, although sometimes higher than, 30%.

Id. at ¶¶ 260-62.

Accordingly, for Remicade Plaintiffs proposed several different measures of damages.

See id. at ¶¶ 254-73.

- As with other drugs, Dr. Hartman employed a threshold of 30% *i.e.*, he did not estimate the damages until the “spread” between AWP and ASP equaled or exceeded 30%. Using that approach and for the Class Period 1999-2003, the

Massachusetts-only damages, without interest for Remicade totaled \$236,791. Ex. 23 (Direct Testimony of Raymond S. Hartman, Attach. J.3.a).

- Alternatively, Dr. Hartman also provided a “5% margin analysis”, *i.e.*, an analysis under which the artificial WAC-to-AWP markup of .30 exceeded the highest insurer markup for retail branded drugs of .25. Ex. 24 (Hartman Rebuttal, Attach. B); Ex. 25 (PX 4066). This resulted in \$191,593,208 in damages nationally.

Finally, the Court could have awarded damages based on the dollars doctors earned on J&J’s drugs. Dr. Hartman calculated this to be \$853,392,342 on Procrit and \$669,146,331 on Remicade during the Class Period. Ex. 25 (PX 4066).

In its Findings of Fact and Conclusions of Law, the Court applied Dr. Hartman’s benchmark to Class 2 and Class 3. It refused to apply Plaintiffs’ *per se* rule for Class 2 to any defendant, including J&J. *See In re AWP*, 491 F. Supp. 2d at 97. The Court likewise rejected Plaintiffs’ arguments that it should apply a different benchmark or a different measure of damages for Class 3 Remicade®, but in doing so the Court admitted that “[t]his is a close call.” *Id.* (emphasis added). Indeed, as the First Circuit remarked, “[t]he court also found in its post-trial order that the issue of what liability trigger to use for Remicade – an issue that turned on ascertaining the appropriate industry expectations – was a ‘close call,’ *In re Pharm.*, 491 F. Supp. 2d at 104, “*thus indicating that, had the court applied the Rule 56 standards, it might well have found there to exist a genuine issue of material fact.*” *In re AWP*, 582 F.3d at 237 (emphasis added).

III. SUMMARY JUDGMENT STANDARD

Summary judgment is appropriate when the pleadings, depositions, answers to interrogatories, and admissions of file, together with affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. *Barbour v. Dynamics Research Corp.*, 63 F.3d 32, 36 (1st Cir. 1995) (quoting Fed. R. Civ. P. 56(c)). “To succeed [in a motion for summary judgment], the moving party must show

that there is an absence of evidence to support the nonmoving party's position." *Rogers v. Fair*, 902 F.2d 140, 143 (1st Cir. 1990); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986).

In deciding a motion for summary judgment, the Court must "view the facts in the light most favorable to the non-moving party, drawing all reasonable inferences in that party's favor."

Barbour, 63 F.3d at 36.

IV. ARGUMENT

A. Summary Judgment is Inappropriate Because Government "Knowledge" Cannot be Imputed to Class 1

The primary basis for J&J's Motions is that the Court should enter summary judgment because the "knowledge" of the Government can be imputed to members of Class 1.³ J&J's argument fails because (1) as a matter of law the knowledge of the Government should not be imputed to Class 1; (2) no members of Class 1 knew that J&J's AWP's were inflated; and (3) there are genuine issues of material fact with regard to J&J's concealment of its conduct from the Government.

1. J&J's imputation theory has been previously rejected by this Court and otherwise fails.

J&J's imputation argument has already been rejected by this Court in the context of Class 2. In response to the Track 1 Defendants' argument that the Government's "knowledge" should be applied to Class 2 for the same reason J&J seeks to impute that knowledge to Class 1, the Court held: "Defendants make a strained argument that Medicare's knowledge of mega-

³ J&J claims the relevant knowledge to be imputed is the Government's alleged knowledge of "modest spreads." In support of this statement, it quotes the First Circuit's opinion out of context, claiming that "[t]his case was never about whether industry and government knew that there were 'modest spreads (such as those created by prompt-pay discounts or formulaic markups from other published prices.)'" J&J Mass. MSJ at 6 (quoting in part *Blue Cross Blue Shield of Mass. v. AstraZeneca Pharm. LP*, 582 F.3d 156, 172 (1st Cir. 2009)). J&J similarly selectively quotes this Court's opinion in *In re AWP*, 230 F.R.D. 61, 71 (D. Mass. 2005), for the proposition that the critical dispute was whether "the government and industry were aware of the *magnitude* of the spread." J&J Mass. MSJ at 7 (emphasis in original). On the contrary, this case was clearly never just about government knowledge of any kind, but was also about the Government's ability to act on that knowledge.

spreads should be imputed to the TPPs in the MediGap Class. However, Medicare was not the agent of the TPPs that had contracts to reimburse beneficiaries, and Medicare did not set or approve drug prices.” *In re AWP*, 252 F.R.D. at 97 n.32. The same thing can be said here: Medicare was not the agent of its beneficiaries and did not act in the rate-setting capacity J&J implies. Medicare never set or approved drug prices.

In an attempt to take a new tack on the Track 1 Defendants’ imputation argument, J&J wrongfully equates the relationship of the Medicare program to its beneficiaries with the relationship between a physician and a patient, and therefore argues that imputing the knowledge of the Government to Medicare beneficiaries is like imputing the knowledge of a physician to patient pursuant to the “learned intermediary” doctrine. J&J’s analogy is inapt for several reasons. As the First Circuit has explained:

The rationale underlying the prescription drug rule is that the prescribing physician, as the ‘learned intermediary’ standing between the manufacturer and consumer/patient, is generally in the best position to evaluate the potential risks and benefits of ingesting a certain drug and to advise the patient accordingly. Under this doctrine, the manufacturer’s duty is fulfilled once it adequately warns the physician.

Garside v. Osco Drug, Inc., 976 F.2d 77, 80 (1st Cir. 1992) (citations omitted). This Court has further explained:

[T]he manufacturer’s immunity from liability if the consumer does not receive the warning is explicable on the grounds that the intermediary’s failure to warn is a superseding cause of the consumer’s injury, or, alternatively, that, because it is unreasonable in such circumstances to expect the manufacturer to communicate with the consumer, the manufacturer has no duty directly to warn the consumer.

MacDonald v. Ortho Pharm. Corp., 475 N.E.2d 65, 68 (Mass. 1985) (citations omitted) (interpreting Massachusetts law).

The application of such a doctrine here is inappropriate because, unlike the intermediary physician who is in a position to protect his or her patient, the Government was not in a position to protect Medicare beneficiaries. *See In re AWP*, 491 F. Supp. 2d at 31 (“neither the third party payors nor the government could move quickly or effectively to fix the problem.”); *id.* at 94-95 (“Moreover, defendants knew that neither the government nor the TPPs could do much to change the AWP reimbursement benchmark because they were locked into the nationwide reimbursement scheme established by statute or contract.”).

In addition, courts have been loath to extend the learned intermediary doctrine beyond its specific definition. As this Court found when a group of plaintiffs who brought RICO and various state-law claims against defendants who made alleged misrepresentations regarding phenolic foam roof insulation attempted to expand the learned intermediary doctrine into a theory permitting plaintiffs to allege a claim of “indirect reliance” on representations made to a third party:

Plaintiffs’ invocation of the ‘learned intermediary doctrine’ is not persuasive. Under the learned intermediary doctrine, when a drug or medical manufacturer directs a warning to a ‘learned intermediary,’ such direction is a defense to a failure-to-warn products liability claim even if the learned intermediary never communicated the warning to plaintiff. [Citation omitted.] Because the learned intermediary doctrine only provides a defense in failure to warn cases involving drugs and medical supplies, the plaintiffs cannot rely upon it here as a basis for this court to adopt a more expansive theory of indirect reliance that the Maine SJC has ever indicated is justified.

Sebago, Inc. v. Beazer East, Inc., 18 F. Supp. 2d 70, 88 n.8 (D. Mass. 1998) (interpreting Maine law).

Finally, applying the learned intermediary doctrine as J&J suggests would imply that the overpayments made by Class 1 were attributable to the Medicare program. Instead, they were attributable to J&J’s conduct. *See In re AWP*, 582 F.3d at 177 (“In comparison, this case

involves neither misrepresentations made directly to HCFA nor any concerns similar to the administrative efficiency concerns noted by the *Buckman* court. Perhaps more conclusively, unlike *Buckman*, this case cannot be said to involve disclosures that are fairly understood as to have been “deemed appropriate by the Administration.” At issue here is a state law remedy for deceptive practices by a manufacturer against its customers. It is certainly true that the deception touched on a federal agency, but policing deceptive conduct is nonetheless a traditional area of state concern giving rise to a remedial scheme that is separate and distinct from, and predates, the federal law in question.”); *In re AWP*, 263 F. Supp. 2d 172, 189 (D. Mass. 2003) (“Therefore, the decision of the pharmaceutical companies, not an agency action, is alleged to cause plaintiffs’ harm.”).⁴

2. The relevant inquiry is the knowledge of members of Class 1.

Because any knowledge of the Medicare program cannot be imputed to Class 1 as a matter of law, the relevant question is the knowledge of the members of Class 1.

J&J misses the mark here as well. In essence, J&J argues that because members of Class 1 had no expectation regarding what AWP should mean, the Court cannot adopt a damages methodology, or allow a jury to consider a damages methodology, that is based on those expectations. But J&J oversimplifies the testimony of the class representatives regarding what they expected AWP to mean. Namely, although the class representatives did not know what AWP specifically meant, they *did* expect that the prices they paid would not be unlawfully or fraudulently inflated. Nor did they expect that J&J’s business practices would lead to their

⁴ J&J’s imputation argument should also be rejected because it is merely a thinly-disguised reargument of its government knowledge defense, which was rejected by the Court during the Class 2/Class 3 bench trial. J&J’s argument begs the question of what precisely should be imputed to Class 1 – a question that improperly invites the Court to reconsider its previous rulings rejecting the government knowledge defense. The door is closed on that defense. See *Piazza v. Aponte Roque*, 909 F.2d 35, 38 (1st Cir. 1990); *Employers Ins. of Wausau v. First State Ins. Group*, 324 F. Supp. 2d 333, 338 (D. Mass. 2004).

physicians making decisions about which drug to prescribe based on the profitability of those drugs. *See* Plaintiffs' Rule 56.1 Counter-Statement Nos. 1 and 2. This is an expectation shared by all members of the Class, and a damages methodology can be presented to the jury on that basis. *See In re AWP*, 230 F.R.D. at 82 ("There is therefore no separate factual issue regarding the knowledge and reliance of each class member."); *id.* at 85 ("[I]n this context, where consumers (elderly people with cancer or another serious disease) make a percentage co-payment based on the stated AWP, there is no indication that different definitions of reliance and causation will matter or cannot be resolved as a matter of law prior to trial.").

3. Even if the Court holds that the knowledge of the Government may be imputed to Class 1, there are genuine issues of material fact regarding J&J's attempts to conceal its conduct from the Government.

Even if the Court holds that the knowledge of the Government or the Medicare program may be imputed to Class 1, there are, at minimum, genuine issues of material fact regarding J&J's attempts to conceal its conduct from the Government that preclude the entry of summary judgment.⁵ J&J argues that "for drugs with moderate spreads within the range that HCFA and Congress expected, the government was not duped." J&J Mass. MSJ at 11. But this ignores that, rather than informing Congress that its marketing practices were leading to spreads between its AWP's and ASPs, J&J sought to hide its real prices from the Government. *See* Plaintiffs' 56.1 Counter-Statement No. 4. *Cf. Lareau v. Page*, 840 F. Supp. 920, 932 (D. Mass. 1993) ("[Plaintiff's] arguments fail. *Garside [v. Osco Drug, Inc.]*, 976 F.2d 77 (1st Cir. 1992)) is, of course, factually distinguishable since there it was undisputed that the defendant pharmaceutical

⁵ J&J points out that this Court acknowledged that Defendants never argued that AWP meant a 20 to 25% mark-up from WAC, even though the industry practice of using those mark-ups was "arguably relevant in construing the meaning of the statutory term AWP." J&J Mass. MSJ at 3 n.1 (quoting *In re AWP*, 491 F. Supp. 2d at 97 n.72). While that practice may, indeed, have been relevant to construing AWP, it is not relevant to determining "government knowledge" or the knowledge of Class 1 because, as this Court found, the Government (and similarly Class 1) could not have quickly acted to change those – or any other – spreads.

company failed to warn the defendant physician.”) (citation omitted), *aff’d*, 39 F.3d 384 (1st Cir. 1994). J&J fails to account for the evidence that it actively *concealed* its conduct.

B. The Court Cannot Enter Summary Judgment Against Members of Class 1 Who Reside in States That Require Trial By Jury

Even if the Court does not deny both J&J’s motions for summary judgment on the grounds that any “knowledge” of the Government cannot be imputed to Class 1, it should deny J&J’s motion for members of Class 1 who reside in states that require trial by jury. J&J’s nationwide brief is based on the facile argument that, because the Court certified a nationwide Class of Medicare beneficiaries because doing so would promote a “uniformity of results” across the states, the Court should treat the laws under all those states as the same and therefore enter summary judgment in favor of J&J and against members of Class 1 who reside in states other than Massachusetts. J&J Nationwide MSJ at 2.⁶ J&J’s argument ignores that the Seventh Amendment prohibits the Court from taking the roles of determining disputed issues of fact and damages from the jury.

There is no dispute that most of the state laws under which Class 1 was certified require that claims brought by consumers such as the Medicare beneficiaries that comprise Class 1 to be tried to a jury.⁷ The right to a jury trial is guaranteed by the Seventh Amendment of the

⁶ J&J claims that further evidence of the reason the Court should apply its Massachusetts summary judgment ruling to the entire Class is because the Court previously granted partial summary judgment in favor of the Track 1 Defendants when it cut off the class period when Congress enacted the MMA. J&J Mass. MSJ at 10-11. However, the Court did not cut off the class period at the enactment of the MMA because it held that the Government’s knowledge should be imputed to any Class members (indeed, the Court held that the Government had knowledge of the offending conduct *before* the enactment of the MMA); rather, the Court held that at the time the MMA was enacted AWP had become a “term of art” (*In re AWP*, 460 F. Supp. 2d at 288) and therefore had “an established and settled meaning.” *Id.* at 285.

⁷ See, e.g., ARIZ. REV. STAT. § 44-1521, *et seq.*; ARK. CODE ANN. § 4-88-101, *et seq.*; COLO. REV. STAT. § 6-1-101, *et seq.*; CONN. GEN. STAT. § 42-110, *et seq.*; 6 DEL. CODE § 2510, *et seq.*; D.C. CODE § 28-3900, *et seq.*; FLA. STAT. § 501.204; HAW. REV. STAT. § 480-1, *et seq.*; IDAHO CODE § 48-601, *et seq.*; IND. CODE. § 24-5-0.5, *et seq.*; KAN. STAT. ANN. § 50-624, *et seq.*; MD. COM. LAW CODE § 13-101, *et seq.*; MICH. COMP. LAWS § 445.901, *et seq.*; MINN. STAT. § 325F.69, *et seq.*; MO. REV. STAT. § 407.010, *et seq.*; NEV. REV. STAT. § 598.090, *et seq.*; N.H. REV. STAT. § 358-A:2, *et seq.*; N.J. STAT. § 56:8-1, *et seq.*; N.M. STAT. § 57-12-1, *et seq.*; N.Y. GEN. BUS. LAW. § 349, *et seq.*; N.C. GEN. STAT. § 75-1.1, *et seq.*; N.D. CENT. CODE. § 51-15-101, *et seq.*; OHIO REV. CODE § 1345.01, *et*

Constitution. “Maintenance of the jury as a fact-finding body is of such importance and occupies so firm a place in our history and jurisprudence that any seeming curtailment of the right to a jury trial should be scrutinized with the utmost care.” *Beacon Theatres, Inc. v. Westover*, 359 U.S. 500, 501 (1959) (citation omitted).

“[I]n civil actions, our federal judicial system ‘distributes trial functions between judge and jury and, under the influence – if not the command – of the Seventh Amendment, assigns the decisions of disputed questions of fact to the jury.’ . . . ‘[W]hen facts are in dispute, ‘we doubt the Supreme Court intended this dispute to be resolved from the bench by fiat.’” *Jennings v. Jones*, 499 F.3d 2, 10 (1st Cir. 2007) (internal citations omitted), *cert. denied*, 552 U.S. 1170 (2008).

“In the federal system, a trial judge does not sit as a super-juror, free to disregard the considered verdict of a properly instructed jury ‘merely because he disagrees with it or would have found otherwise in a bench trial.’” *Quinones-Pacheco v. American Airlines, Inc.*, 979 F.2d 1, 3 (1st Cir. 1992) (citation omitted).⁸ As the Supreme Court explained many years ago:

It is not the function of a court to search the record for conflicting circumstantial evidence in order to take the case away from the jury on a theory that the proof gives equal support to inconsistent and uncertain inferences. The focal point of judicial review is the reasonableness of the particular inference or conclusion drawn by the jury. It is the jury, not the court, which is the fact-finding body. It weighs the contradictory evidence and inferences, judges the credibility of witnesses, receives expert instructions, and draws the ultimate conclusion as to the facts. The very essence of its function is to select from among conflicting inferences and conclusions that which it considers most reasonable.

seq.; OKLA. STAT. TIT. 15, *et seq.*; OR. REV. STAT. § 646.601, *et seq.*; 73 PENN. STAT. § 201-1, *et seq.*; R.I. GEN. LAWS. § 6-13.1-1, *et seq.*; S.C. CODE § 39-5-20, *et seq.*; S.D. CODIFIED LAWS § 37-24-1, *et seq.*; TENN. CODE § 47-18-101, *et seq.*; TEX. BUS. & COM. CODE § 17.45, *et seq.*; UTAH CODE § 13-11.10, *et seq.*; VT. STAT. ANN. TIT. 9, § 2400, *et seq.*; WASH. REV. CODE § 19.86.010, *et seq.*; W. VA. CODE § 46A-6-101, *et seq.*; WIS. STAT. § 100.18, *et seq.*; WYO. STAT. § 40-12-101, *et seq.*

⁸ Federal law determines the relationship between judge and jury, “including the standard – that no reasonable jury could find otherwise.” *Bezanson v. Fleet Bank – NH*, 29 F.3d 16, 20 (1st Cir. 1994).

Gallick v. Balt & O.R. Co., 372 U.S. 108, 114-15 (1963) (citations omitted).

For example, the Court analyzed three factors at trial in determining whether J&J's conduct was "unfair" under Chapter 93A. *In re AWP*, 491 F. Supp. 2d at 101. Once properly instructed on the law, the jury could consider different factors, or weight the factors the Court used differently. For example, a jury might weigh the vulnerability of the Class, the extensive evidence of J&J's spread marketing, or any number of factors in making its decision. But it is the jury that is entitled to decide issues of disputed fact.

In addition, juries' determinations regarding damages are entitled to great deference: in this Circuit a district court may grant a new trial on damages "only when the award 'exceeds any rational appraisal or estimate of the damages that could be based upon the evidence before it.'" *Eastern Mountain Platform Tennis, Inc. v. Sherwin-Williams Co.*, 40 F.3d 492, 502 (1st Cir. 1994) (citation omitted). *See also Rivera v. Turabo Med. Ctr. P'Ship*, 415 F.3d 162, 173 (1st Cir. 2005) ("A party seeking remittitur bears a heavy burden of showing that an award is grossly excessive, inordinate, shocking to the conscience of the court, or so high that it would be a denial of justice to permit it to stand.") (citation omitted); *Larch v. Mansfield Mun. Elec. Dep't*, 272 F.3d 63, 73 (1st Cir. 2001) ("An award of damages will not be deemed unreasonably high as long as it comports with some rational appraisal or estimate of the damages that could be based on the evidence before the jury' and is not 'grossly excessive, inordinate, shocking to the conscience of the court, or so high that it would be a denial of justice to permit it to stand.'") (citations omitted).

Particularly relevant here, while the Court is the gatekeeper of expert testimony (*Daubert v. Merrell Dow Pharms.*, 509 U.S. 579, 592 (1993)), once deemed admissible, it is the jury's role to determine the credibility and weight of that testimony. *Peckham v. Continental Cas. Ins. Co.*,

895 F.2d 830, 838 (1st Cir. 1990) (“Despite plaintiffs’ sarcastic assault upon the experts’ opinions, it was for the jury to determine what weight and value, if any, should be assigned to them.”); *Marshall v. Perez Arzuaga*, 828 F.2d 845, 852 (1st Cir. 1987) (“Avis raises challenges to a host of specific opinions and statements made by Rosenbluth, claiming that they were contrary to proven facts, based on guesswork, or were otherwise misleading. We do not find that any of these statements or opinions were so utterly unsupported by the evidence to warrant reversing the district court’s decision to allow them into evidence. Avis’s arguments, which went to the logic, coherence, and weight of the expert’s testimony rather than its admissibility, were properly left to the jury to consider.”).

In *Payton v. Abbott Labs*, 780 F.2d 147 (1st Cir. 1985), the jury rendered a verdict for damages. The district court subsequently, on defendant’s motion for judgment n.o.v. or alternatively for a new trial, set aside a jury finding but refused to order a new trial on damages. The First Circuit reversed, holding that “[w]e think that a new trial is mandated. The defendant had the right to have the damages assessed by the jury.” *Id.* at 151. The court concluded that “[t]he trial judge should not act merely as a ‘13th juror’ and set aside a verdict simply because he would have reached a different result had he been the trier of fact.” *Id.* at 153 (citations omitted).

Similarly, in *Marcoux v. Shell Oil Prods. Co. LLC*, 2008 U.S. App. LEXIS 8393 (1st Cir. Apr. 18, 2008), the First Circuit upheld a jury’s damages determination in an action brought under the Petroleum Marketing Practices Act, 15 U.S.C. §§ 2801-2806. Even though the First Circuit recognized the possibility that the jury may have used inaccurate figures from which to calculate damages, the jury’s determination was not beyond what a rational jury could have decided. *Id.* at *46-49. *See also Children’s Broad. Corp. v. Walt Disney Co.*, 357 F.3d 860, 864, 866 (8th Cir. 2004) (“[T]he jury was entitled to sort through the evidence presented at trial and to

arrive at what it considered to be the damages caused by the conduct it found to be wrongful.”) (sustaining jury verdict because, among other things, jury could have adopted any one of expert’s benchmarks regarding how quickly defendants’ misappropriation of trade secrets accelerated its entry into new market).

Prior to trial, Plaintiffs advocated two separate damages methodologies, one for Class 2 (the *per se* approach) and one for Class 3 (Dr. Hartman’s 30% yardstick). After trial, Plaintiffs advocated yet another approach for Class 3 Remicade® damages and yet another method for calculating Class 3 damages generally (by reference to return to practice given to physicians who prescribed J&J’s drugs). While J&J makes much of this Court’s determination that Classes 2 and 3 did not suffer any damages under Dr. Hartman’s 30% benchmark methodology, Dr. Hartman’s 25% methodology resulted in \$191,593,208 in damages nationally for Remicade alone. The return to practice dollars for J&J’s drugs were also substantial: \$853,392,342 on Procrit and \$669,146,331 on Remicade during the Class Period. A reasonable jury could have adopted any one of these approaches in determining Class 1 damages, or could have disregarded all of them and chosen one of J&J’s theories, or chosen a theory of its own.⁹ In the states where Class 1 is entitled to a jury on its claims, it is the jury that must make that choice.¹⁰

⁹ At trial Dr. Hartman testified that his 30% benchmark did not relate to consumers. *See* Ex. 22 (Trial Tr. Day 9 (11/21/06) at 42:7-10) (“Q: Dr. Hartman, your 30 percent expectation yardstick doesn’t relate to consumers, does it? It relates to third-party payors, correct? A: That’s correct.”).

¹⁰ On appeal, J&J argued before the First Circuit that this Court’s decision to adopt Dr. Hartman’s 30% yardstick was a “‘legal’ (and therefore outside the purview of the jury)” determination. *In re AWP*, 582 F.3d at 237. The First Circuit rejected this characterization, finding that it “fail[ed] to account for the fact that the creation of the 30% trigger depend[ing] on *factual* findings relating to the relevant expectations as to the size of spreads.” *Id.* (emphasis in original).

C. The Court Cannot Dismiss the Remaining State Law Claims on the Individual Grounds J&J Raises¹¹

In its nationwide motion J&J argues that all of the remaining claims brought by Class 1 against J&J should be dismissed. J&J argues that, because Massachusetts' Chapter 93A is "one of the most pro-consumer statutes in the country" (*id.* at 12), if Plaintiffs could not prove their Class 2/Class 3 case against J&J under that statute, they will not be able to do so under other states' laws brought by Class 1. This ignores the fact that many of the claims of which J&J seeks dismissal provide for a jury trial, and that the measure of Class 1's knowledge is different than the measure of the knowledge of Class 2 or Class 3.

1. Class 1 has suffered injury.

J&J seeks dismissal of Class 1's claims in Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Idaho, Illinois, Kansas, Maryland, Michigan Missouri, Nebraska, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Dakota, Utah, Washington, Wisconsin and Wyoming on the basis that all those states require Plaintiffs to prove that they suffered a cognizable loss. For the purpose of this Opposition, Plaintiffs do not quibble with that characterization;¹² however, all of those states except California, Illinois and Nebraska require a jury trial. For the reasons set forth above, the Court cannot enter judgment in those states because whether Class 1 experienced a "loss," however defined, must be decided by the jury. The Court likewise cannot enter judgment

¹¹ Plaintiffs concede that neither Tennessee nor South Carolina should be included in Class 1. Indeed, this Court excluded those states from its nationwide certification order with regard to AstraZeneca and BMS because the Tennessee Supreme Court has held that the Tennessee Consumer Protection Act does not permit class actions and the state of the law in South Carolina was too uncertain to support certification. *See In re AWP*, 252 F.R.D. at 95 n.8. Plaintiffs likewise concede, as they acknowledged in their motion to seek nationwide certification of their Class 2 and Class 3 claims against AstraZeneca, that Ohio and Utah have uniquely onerous elements in the context of a class action. *See id.* at 95. Plaintiffs also concede their claim under CAL. CIV. CODE § 1770 because this Court rejected Plaintiffs' proposed grouping of statutes that prohibit misrepresentations about the characteristics of goods. *Id.*

¹² During the October 8, 2009 status conference, the Court stated that it would like Plaintiffs to submit a trial plan. Once Plaintiffs know the claims that remain, they will promptly submit one.

against Class 1 members in California, Illinois or Nebraska because, as set forth above, especially reading the evidence in the light most favorable to the Plaintiffs, it cannot impute the knowledge of the Government to Class 1 to bar its claims under those statutes.

2. The Court should not dismiss the claims of Class 1 in states that do not require a jury.

J&J argues that the Court should dismiss Class 1's claims under Illinois, New Hampshire, Nebraska and California law because they do not provide for a trial by jury, and under North Carolina law because under that statute the court determines whether the defendants' acts or practices are deceptive or unfair. For the reasons set forth above the Court cannot impute the knowledge of the Government to Class 1, and these claims should not be dismissed.¹³

3. The Court should not dismiss the claims of class members in states that require proof of reliance.

J&J claims that the Court should dismiss the claims of class members in Arizona, California, Indiana, Maryland, Michigan, Minnesota, North Carolina, Oregon, Pennsylvania, South Dakota and Wyoming because the consumer protection statutes in those states require proof of reliance. J&J's arguments should be rejected.

Of the foregoing states, only Arizona, Indiana, North Carolina, Pennsylvania, and Wyoming required reliance as Defendants posit. But even in these states, Plaintiffs can establish reliance. Medicare beneficiaries were required by federal regulation in 1991 and federal statute in 1997 to pay 20% of a price based on an inflated AWP. For this reason, in certifying a *nationwide* Class 1, the Court held that "[t]here is therefore no separate factual issue regarding the knowledge and reliance of each class member." *In re AWP*, 230 F.R.D. at 82. The Court explained that "in this context, where consumers (elderly people with cancer or another serious

¹³ Having the Court determine whether J&J's conduct was unfair by analyzing whether its spreads exceeded 30% (one of the factors the Court used in determining "unfair" conduct at trial, *In re AWP*, 491 F. Supp. 2d at 101) would arguably circumvent the requirement under North Carolina law that the jury determine damages.

disease) make a percentage co-payment based on the stated AWP, there is no indication that different definitions of reliance and causation will matter or cannot be resolved as a matter of law prior to trial.” *Id.* at 85. As explained above, J&J equates Medicare beneficiaries’ lack of understanding of AWP with a lack of reliance on those AWPs. J&J’s equation fails. Members of Class 1 had the choice of paying based on inflated AWPs or not taking Procrit or Remicade at all. That is more than sufficient to prove reliance.¹⁴

Moreover, J&J’s representations about the law of several of those states misses the mark. Michigan does not require proof of individual reliance but instead only requires proof that any reliance was reasonable. *See Van Vels v. Premier Ath. Ctr.*, 182 F.R.D. 500, 509 (W.D. Mich. 1998) (“Unlike common law fraud, misrepresentation claims under the MCPA do not require proof of individual reliance.”); *Dix v. American Bankers Life Assur. Co.*, 415 N.W.2d 206, 209 (Mich. 1987) (“It is sufficient if the class can establish that a reasonable person would have relied on the representations. Further, a defendant’s intent to deceive through a pattern of misrepresentations can be shown on a representative basis under the Consumer Protection Act.”).

As for Minnesota, J&J confused causation with reliance. The required causal nexus under Minnesota law could easily be established by showing that Plaintiffs’ purchases of J&J’s drugs were made on the basis of an inflated AWP. *See Group Health Plan, Inc. v. Philip Morris*, 621 N.W.2d 2, 14 (Minn. 2001) (“[W]e do not interpret the language of subdivision 3a to require a strict showing of direct causation, as would be required at common law. Rather, as the court of appeals has expressed it, the statute requires that there must be some ‘legal nexus’ between the injury and the defendants’ wrongful conduct.”). *See also id.* at 15 (“To impose a requirement of

¹⁴ J&J claims that the relationship of Class 1 to Medicare is the same as the relationship of co-insurance consumers in Class 3 to their TPPs. J&J Nationwide MSJ at 23. However, the Court has already distinguished between consumer members of Class 3, who may be represented by their TPPs, and consumer members of Class 1, who cannot. *See In re AWP*, 230 F.R.D. at 80.

proof of individual reliance in the guise of causation would reinstate the strict common law reliance standard that we have concluded the legislature meant to lower for these statutory actions. Moreover, we are confident that the legislature would not have authorized private damages actions such as this, where the alleged misrepresentations are claimed to have affected a large number of consumers, while retaining a strict burden of proof that depends on evidence of individual consumer reliance.”).

Although the Oregon act requires reliance in cases of affirmative misrepresentation, reliance in cases of omission is not required. *Sanders v. Francis*, 561 P.2d 1003, 1006 (Or. 1977), like, for example, with regard to J&J’s failure to disclose its spread marketing activities. A similar interpretation should be given to the Maryland act, given that the court in *Philip Morris, Inc. v. Angeletti*, 752 A.2d 200, 235 (Md. 2000), only held that reliance was required in circumstances of affirmative misrepresentations.

South Dakota does not require reliance. The court in *Northwestern Pub. Serv. v. Union Carbide Corp.*, 236 F. Supp. 2d 966, 973 (D.S.D. 2002), mistakenly held that reliance was required, for it did not cite any South Dakota supporting authority and ignored the plain terms of the statute which states, in part, “whether any person has in fact been misled, deceived, or damaged thereby.” S.D. CODIFIED LAWS § 37-24-6(1).

Finally, CAL. BUS & PROF. CODE § 17200 does not require all unnamed class members in a UCL class action to demonstrate § 17204 standing, but rather only that the representative plaintiff(s) establish such standing. *In re Tobacco II Cases*, 207 P.3d 20, 32 (Cal. 2009). Further, causation is established if there is a sufficient causal nexus between the injury and the false representation. “‘It is not ... necessary that [the plaintiff’s] reliance upon the truth of the fraudulent misrepresentation be the sole or even the predominant or decisive factor in

influencing his conduct.... It is enough that the representation has played a substantial part, and so has been a substantial factor, in influencing his decision.” *Id.* at 39 (internal citations omitted). For the reasons set forth above, Class 1 would clearly meet these standards.

4. The Court should not enter summary judgment against Class members in states that prohibit deceptive acts, unfair conduct, or conduct that is unconscionable.

J&J next argues that the Court should not enter summary judgment against Class members in states that prohibit deceptive acts, unfair conduct, or conduct that is unconscionable. For the reasons stated above, this argument does not apply to any states other than California, Illinois, New Hampshire and Nebraska because all other states require jury trials. In addition, this argument does not apply to the remaining states because the knowledge of the Government cannot be imputed to Class 1. In addition, J&J says that summary judgment can be entered because “the J&J Defendant did not make deceptive statements to consumers, as consumers were never exposed to published AWP’s.” The Court long ago rejected that argument, because consumers paid by law based on AWP.

Moreover, J&J’s argument that the Court can enter summary judgment for those Class 1 members in statutes that prohibit unconscionable conduct (Arkansas, Florida, Idaho, Kansas, New Jersey, New Mexico and Texas) fails because the Court has never made findings regarding whether J&J’s conduct was unconscionable that can be applied to the consumer members in these states.

5. The Court should not enter summary judgment against Class members in states that require the relevant misrepresentation to be material.

Finally, J&J argues that the Court should enter summary judgment against Class members in California, Connecticut, District of Columbia, Hawaii, Illinois, Kansas, Maryland,

Michigan, New Jersey, New York, Pennsylvania,¹⁵ Texas and Vermont because those states require the relevant representations to be material. As an initial matter, whether a representation is material is a question of fact for the jury, precluding the Court from entering summary judgment for all of the above states except California and Illinois. *Cf. Winters v. Stemberg*, 529 F. Supp. 2d 237, 249 (D. Mass. 2008) (“With regard to the Defendants’ final argument about the materiality of the alleged statements, the First Circuit has held that whether a statement is material is a question of fact for the jury and thus should not be decided by a court in the context of a motion to dismiss.”).¹⁶ Members of Class 1 had the choice of paying based on inflated AWP’s or not taking Procrit or Remicade at all. This makes J&J’s misrepresentations material.

V. CONCLUSION

WHEREFORE, for the reasons set forth above, Plaintiffs respectfully request that this Court DENY the Post-Remand Motions for Summary Judgment filed by the J&J Defendants, and set a date for the claims of Class 1 to be tried.

DATED: January 15, 2010

Respectfully submitted,

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¹⁵ *Colaizzi v. Beck*, 895 A.2d 36, 39-40 (Pa. Super. Ct. 2006), cited by J&J, discusses the materiality element of a common law fraud claim, not a consumer protection claim.

¹⁶ J&J says that this Court can enter judgment because no reasonable jury could conclude that J&J made a material misrepresentation because its AWP’s for Procrit and Remicade tracked its ASPs. This, however, assumes that Plaintiffs intend to use Dr. Hartman’s 30% yardstick for Class 1. They do not.

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CERTIFICATE OF SERVICE BY LEXISNEXIS FILE & SERVE

In re Pharmaceutical Industry Average Wholesale Price Litigation
Master Case No. 01-cv-12257, MDL 1456

I, Steve W. Berman, hereby certify that I am one of Class Plaintiffs' attorneys and that, on January 15, 2010, I caused a copy of *Plaintiffs' Combined Opposition to the J&J Defendants' Post-Remand Motions for Summary Judgment* to be served on all counsel of record by causing same to be posted electronically via Lexis-Nexis File & Serve.

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